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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,652	08/20/2003	Wendy Naimark	10177-185-999	8822
20583	7590	12/12/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			WITCZAK, CATHERINE	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,652

Applicant(s)

NAIMARK ET AL.

Examiner

Catherine N. Witczak

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7, 16 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-33 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-15, 17-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/30/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

12/10/06

DETAILED ACTION

Election/Restrictions

Applicant's arguments, filed 9/28/2006 have been found persuasive and the restriction/election requirement of 8/28/2006 is being withdrawn. As such, claims 1-5, 8-15, 17-19, and 21-33 have been examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 3, 4, 5, 8, 15, 17, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonhardt (US 5,693,029).

Leonhardt discloses in Figure 4 an apparatus comprising a catheter (20) having a lumen; a balloon (30) having an interior compartment (38) containing biologically active material; and a plurality of microneedles (40) having lumens (56) in fluid communication with the interior compartment disposed upon the outer surface of the balloon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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Art Unit: 3767

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 9-14, and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt in view of Yuzhakov et al (US 6,565,532).

Leonhardt discloses the claimed invention except for there being between 10 and 1,000,000 microneedles per cm² on the outer surface of the balloon, with the diameter of the microneedles being between 10nm and 1mm. Yuzhakov et al teach in column 6, lines 41058 that it is known to use microneedles with a diameter between 10nm and 1mm in a density of 10 and 1,000,000 microneedles per cm². It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Leonhardt with microneedles having a diameter and density as taught by Yuzhakov, since such a modification would provide the system with more effective microneedle penetration.

Allowable Subject Matter

Claims 27-33 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons